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09/285,306	04/02/1999	THOMAS GINGERAS	018547-01857	3558

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EXAMINER

SIEW, JEFFREY

ART UNIT PAPER NUMBER

1637

DATE MAILED: 10/28/2002

27

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/285,306

Applicant(s)

GINGERAS ET AL.

Examiner

Jeffrey Siew

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 & 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☒ Other: *STIC 2 pages*.

## **DETAILED ACTION**

### ***Continued Prosecution Application***

1. The request filed on 7/29/02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/285306 is acceptable and a CPA has been established. An action on the CPA follows.

The afterfinal amendment filed 4/4/02 has been entered and considered. Claims 17-20 are cancelled. New claim 21 has been added. The pending claims are **1-16 & 21** of which 1,3,4,7,11 and 21 are independent claims.

### ***Drawings***

2. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 8/1/01 have been approved.

## **INFORMATION ON HOW TO EFFECT DRAWING CHANGES**

### **I. Correction of Informalities -- 37 CFR 1.85**

New formal drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front

Art Unit: 1656

of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

## **II. Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

### **Timing of Corrections**

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

### ***Specification***

3. On page 8 line 18 the URL should be deleted. While in the advisory action of 5/31/02 stated that the proposed amendment would overcome the objection to the specification, upon further review and study of the MPEP 608.1, the objection is maintained.

MPEP 608.01 states

.....Examiners must review patent applications to make certain that hyperlinks and other forms of browser-executable code, especially commercial site URLs, are not included in a patent application. Examples of a hyperlink or a browser-executable code are a URL placed between these symbols "< >" and http:// followed by a URL address. When a patent application with embedded hyperlinks and/or other forms of browser-executable code issues as a patent (or is published as a patent application publication) and the patent document is placed on the USPTO web page, when the patent document is retrieved and

Art Unit: 1656

viewed via a web browser, the URL is interpreted as a valid HTML code and it becomes a live web link. When a user clicks on the link with a mouse, the user will be transferred to another web page identified by the URL, if it exists, which could be a commercial website. USPTO policy does not permit the USPTO to link to any commercial sites since the USPTO exercises no control over the organization, views or accuracy of the information contained on these outside sites.

If hyperlinks and/or other forms of browser-executable code are embedded in the text of the patent application, **examiners should object to the specification** and indicate to applicants that the embedded hyperlinks and/or other forms of browser-executable code are impermissible and require deletion....

The amendment filed 4/4/02 to the specification inserts [www.ncbi.nlm.nih.gov](http://www.ncbi.nlm.nih.gov) still is recognized as live hyperlink in many word processing programs. It is believed that the URL designation still would be interpreted as valid HTML code and would become a live web link. USPTO policy does not permit the USPTO to link to any commercial sites since the USPTO exercises no control over the organization, views or accuracy of the information contained on these outside sites. The objection is maintained.

### ***Claim Rejections - 35 USC § 112***

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 & 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

Art Unit: 1656

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Based on the art that was published after applicant's filing date, the prior art has disclosed a full sequence of rpoB gene of *M. tuberculosis* which was revealed to extend 3,534 base pairs(see Miller et al Antimicrob Agents chemotherapy April 1994 pp. 805-811). There is expected variation among the species of DNA which encode the mycobacterial rpoB gene. SEQ ID Nos 2 -10 are of the sizes 626 or 705bp and each sequence as being indicative of *M. avium* strain (see Table 2). The gene then would have many interspecific and intraspecific differences that would lie within and outside the claimed fragments. The specification has only disclosed only fragments that may be used to distinguish *M. avium* strain from other strains but does not provide support for all variations of the gene that lie outside the fragment. The nature of the variants is that they are variant structures where the structure and function of one does not necessarily provide guidance to the structure and function of others. The disclosure of *M. avium* rpoB fragments do not provide the guidance of the structure and function of the complete gene within the *M. avium* strain and in other strains. The common attributes of the genus, other than SEQ ID Nos 2-10, are not described. Moreover, the lower limit of 100 bases within 3533 base gene would not provide sufficient written description to the wide number of base variations of the varying species that not only lie outside 100 bases as well as the disclosed SEQ ID Nos. The specification would not provide adequate written support for such a claim. One of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only a few fragments of a very diverse genus is not representative of the variants of the genus and is insufficient to support the claim.

It is suggested that the claim be incorporate "consisting of" language.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 3-16 are indefinite because the recitation of the Markush language is unclear in claims 3 & 4,6,7,8,9,10,11,13,15 & 16. Markush language format is selected from "the group consisting of A,B and C". It is recommended that the format in Claim 1 be incorporated for consistency and clarity.

B) The term sequence specific probe is unclear in claim 11. It cannot be determined as to what limitation the phrase brings to the claim. Each sequence containing a set of nucleotides would be specific to the combination set of nucleotides.

Art Unit: 1656

C) Claims 11-16 are indefinite because from the recitation in “the segment includes at least 20 bases .. which differ..”, it is unclear whether the probe is to hybridize to the whole segment that would include the 20 bases or not. (see related art rejection below)

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by De Beenhouwer et al (WO 95/33851 14 December 1995).

De Beenhouwer et al teach a method of simultaneous detection of the antibiotic resistance and identification mycobacterium species (see whole doc.). They teach that isolating and concentrating polynucleic acids in sample, amplify rpoB gene and hybridize with rpoB probes to differentiate several non-M. tuberculosis isolates (see abstract & claim 1). They teach M. avium 5887 rpoB sequence which contains 72 contiguous base pairs (bp252-324) that are complementary to claimed SEQ ID No. 10 (bp219-291) which contains the highlighted bp 245, 251 & 257. They teach M. avian ITG 5887 rpoB sequence which contains 267 contiguous base pairs (bp 57-324) that are 100% complementary to SEQ. ID NO. 7 (bp 24-291) (see Figure 6 & claim 13) which contains the highlighted base pair 32,33,47,50,53,56,59, 93,94,98,129, 131,146,161,164, 167,176 & 179 . They teach a sequence of M. paratuberculosis strain 316F



Art Unit: 1656

rpoB which contains 67 contiguous base pairs (bp 252-319) that are 100% complementary to SEQ. ID NO. 8 (bp201-268) (see Figure 6 & claim 13) which contains highlighted base pair 218. They then teach that these non Tuberculosis sequences were sequenced and compared to rpoB gene sequence of M. tuberculosis in order to develop probes which differentiate M. tuberculosis from other species (see page 30-31). **Specifically they teach a 22 bp oligonucleotide MA-POL-1 which is perfectly complementary bp 41-63 of SEQ ID NO:7 and contains Figure 1's highlighted base pairs 47,50,53,56 & 59 at its 3'end and central region** (see page 40 & Figure 6) and is used to differentiate the strain M. avium (see claim 1, table 2 and page 31 line 1).

The response has amended the claims to refer to hybridization under stringent conditions. Upon further careful parsing of claim 11 and due to the indefiniteness of the claim, the office has endeavored to reasonable interpret the scope of the claims. The scope would encompass De Beenhouwer et al's probe.

Claim 11 recites:

**1. probe or primer that hybridize to at least one segment that differ from SEQ ID NO:1 in at least 20 bases** when maximally aligned.

The claim is drawn to the oligonucleotide that hybridizes to the segment but does not necessarily possess the limitation of being fully complementary to the segment length sufficient to contain at least 20 bases that differ from SEQ ID NO:1. The oligonucleotide may hybridize to **any portion** that hybridizes to such a segment but also may not hybridize to SEQ ID NO:1. De Beenhouwer et al's probe contains a portion which is perfectly complementary to bp 41-63 of

Art Unit: 1656

SEQ ID NO :7 and does contain differing **base pairs 47,50,53,56 & 59 at its 3' end and central region** at its 3' end and central region when maximally aligned (see attached stic report). De Beenhouwer et al teach that the probe is used to differentiate the strain M. avium from other strains including M. tuberculosis which is SEQ ID NO:1. The probe would be expected to satisfy the limitations of the claims in not binding to SEQ ID NO:1 under stringent conditions.

### SUMMARY

6. No claim is allowed. However, claims 3-10 are rejected under 112 second paragraph but free of the prior art. There is no prior art that teach or suggest a probe that consisting of the complement of SEQ ID NO: 2-10 or a method of classifying mycobacteria by comparing at least one SEQ ID NO:2-10 The closest prior art is De Beenhouwer et al who teach fragments less than 100 base pairs complementary to SEQ ID NO:7.

### CONCLUSION

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The


Art Unit: 1656

examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Monica Graves for Art Unit 1637 whose telephone number is (703)-306-2938.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Before Final FAX (703) 872-9306 or After Final FAX (703) 30872-9307.

  
JEFFREY SIEW  
PRIMARY EXAMINER

October 26, 2002